EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

- - -

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	:	HON. DAN A. POLSTER
	:	MDL NO. 2804
APPLIES TO ALL CASES	:	
	:	CASE NO. 17-MD-2804
	:	

- HIGHLY CONFIDENTIAL -
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VOLUME I

- - -

May 16, 2019

- - -

Videotaped deposition of DR. SETH B. WHITELAW, taken pursuant to notice, was held at the offices of Golkow Litigation Services, One Liberty Place, 1650 Market Street, Philadelphia, Pennsylvania beginning at 9:18 a.m., on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

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questions, and you'll answer the questions. I'll let you finish your answers, but please let me finish my questions first.

Your counsel's probably asked you to pause for a few seconds so he can get an objection in.

Plaintiffs' counsel -- or excuse me. If -- if you have any -- please ask me a question if you have any time -- if you have any at any time. If you don't -- if you don't have any concerns or questions with my questions, I'll assume you understood them.

And if you need to take a break at any time, just go ahead and ask and we'll -- we can take a break. I just ask that if a question is pending, that you answer the question before we take a break.

Sound good?

A. Sounds very good.

Q. When were you first contacted by the plaintiffs about

participating as an expert in this litigation?

A. It would have been November, December time frame, 2018. I can't be precise on the date, but to the best of my recollection.

Q. This was last year?

A. Yeah. This would have been last year.

Q. And who contacted you?

A. I honestly don't remember the first contact. But contact came from the law firm of Seeger Weiss.

Q. Did you work with anyone on Seeger Weiss on -- on your report, on preparing your report?

A. Other than providing invoices and things back and forth, no.

Q. Which plaintiffs' counsel have you been working with?

A. I've worked with a number of them --

MR. BOGLE: Object to form.

You can answer.

hour for your work on this litigation?
A. $400 an hour, sir, which is my standard rate.
Q. And is that hourly rate, does it apply to preparation of your report and testifying?
A. Yes, sir, it does.
Q. How much time have you spent on this case so far?
A. I have probably almost 1200 hours in.
Q. So you've billed approximately $480,000 to this case so far; is that right?
A. If you count both billed and unbilled time, yeah, that would be about the right number.
Q. In these 1200 hours, what have you done?
A. In these 1200 hours I've actually produced a 300 -- the report that you have in front of you which you are well aware of. I have looked at six different defendants, from a federal

followed the same uniform approach that I do when I do any kind of a compliance investigation, or compliance assessment.

I use the federal sentencing guidelines as my sort of framework. And I asked counsel, in this case, serving like I would a client, I need documents in these particular areas, could you please provide me with information that relates to these particular areas. And they provided me with those documents.

If I was unclear or I didn't get exactly -- it is an iterative process. So if I was unclear or I didn't get what I was looking for, I asked further follow-up questions. I asked for further information. Once I got that information, I then reviewed it.

Q. What were the original categories of documents that you requested from plaintiffs' counsel?

A. We can turn to my report and we can go down the eight elements of the federal sentencing guidelines if you'd

Q. Have you spoken with any of plaintiffs' other experts?
A. Yes, I have.
Q. Who have you -- which -- which other plaintiffs' experts have you spoken with?
A. I spoke at length with Mr. Rafalski. We had several conversations. Again, his expertise as a DEA agent and certainly what DEA was thinking at the time and how an inspector would approach the controlled substances regulations, were of particular importance and use to me as far as understanding what I was looking at, and having an understanding of the DEA's positions on certain topics.
Q. Did you speak with any of other -- any other of plaintiffs' experts?
A. Not that I can recall, sir.
Q. Do you know Craig McCann?
A. I don't know Craig McCann. I know of Craig McCann.

Q. Have you spoken with Mr. McCann?
A. No, sir, I have not.
Q. Did you provide Mr. McCann with any of your analysis or work?
A. No.
Q. Did you provide Mr. Rafalski with any of your analysis or work?
A. No, I did not provide Mr. Rafalski with any of my analysis or work. I asked him questions, we had telephone conversations.
Q. In preparing your report or reaching any of your opinions, did you speak with anyone from the DEA?
A. Well, I would assume Mr. Rafalski counsel's former DEA, but if you're asking me anybody -- are you asking me the question of anybody currently employed by DEA?
Q. Yes, sir.
A. No, sir, I did not speak to anybody who is currently employed with the Drug Enforcement Administration.

Q. And other than Mr. Rafalski, did you speak with anyone who was formerly employed by the DEA in reaching your opinions?

A. No, sir, he was the only one I spoke with.

Q. Last summer did you attend a meeting with plaintiffs' counsel and several of the other expert witnesses in this case?

A. Last summer?

Q. Last summer.

A. Can you -- can you be more specific on last summer?

Q. June 2018.

A. No, sir, I did not. As I said to you, I wasn't -- they didn't reach out to me until November 2018.

Q. Have you attended any -- any meetings with plaintiffs' counsel and other plaintiffs' experts in this case since you were retained in November of 2018?

A. Could you say that question

A. DEA compliance programs, as we will -- as noted in my report, are a subset of the larger corporate compliance program.

So you have a corporate compliance program. You have an anti-diversion program under that. You have a suspicious order monitoring program under that.

So it's all sort of a subsumed in the bigger picture. We are talking compliance, we are talking compliance with all laws and regulations, the systems and processes designed at the corporate level.

Q. Have you designed a DEA compliance program before?

A. I have not designed a DEA compliance program in the sense of a controlled substances. I have designed a sample and sample accountability PDMA compliance programs. As you know, those are substantially similar programs. You need to know who you are selling -- you

would have been a long time ago. First time I read it? A long time ago.

Q. You worked as an intern at the office of chief counsel at FDA?

A. I did for a period of time.

Q. It was for one year, correct?

A. Correct.

Q. That was from 1988 to 1989?

A. That is correct.

Q. And then you took an associate position at Fox Bennett & Turner?

A. Mm-hmm.

Q. That was your first position after law school, right?

A. Yeah. That would have been correct.

Q. And Fox Bennett & Turner is a private law firm?

A. Yes. Was originally Fox Weinberg & Bennett. Is now -- it was then Fox Bennett & Turner. I have no idea what it's evolved into now, If the

firm is even still in existence at this point.

Q. Your work at the Fox Bennett & Turner firm was on food, drug, and environmental issues, correct?

A. Correct.

Q. After a year at Fox Bennett & Turner, you moved to the company of FD Inc.?

A. Mm-hmm.

Q. And you were the head of sales and marketing?

A. I did.

MR. BOGLE: Make sure you say yes or no rather than "mm-hmm," just sort of -- so the record is clear. The court reporter will get onto you a little.

THE WITNESS: Thank you.

MR. BOGLE: She's nice, but...

THE WITNESS: I'll try to do better.

A. Never -- my time, never manufactured stents. Surgical catheters, yes. Feeding tubes, yes. Urological catheters, yes. Other specialty catheters, yes. And electrophysiology devices. It was a whole host of devices.

Q. C.R. Bard is not a wholesale drug distributor, is it?

A. Not by the definition of what a wholesale drug distributor is, no.

Q. C.R. Bard does not manufacture opioids?

A. At least not when I was there, no they did not.

Q. C.R. Bard does not distribute opioids?

A. Not when -- during the time that I was present.

Q. Or any other controlled substance?

A. To the best of my knowledge, again, not when I was there.

Q. Did you provide any compliance advice regarding the

Q. But the policies focus on providing samples to physicians, that's true, correct?

A. That -- that is true.

Q. Now, SmithKline was --

A. Or other -- other prescribers, so let's be clear. You can have nurse practitioners, or physician's assistants, who also have prescribing privileges. We could provide samples to them.

Q. Thank you for that.

SmithKline was a pharmaceutical manufacturer, right?

A. That is correct.

Q. SmithKline was not a wholesale drug distributor?

A. No, sir, it was not.

Q. SmithKline did not manufacture opioids, correct?

A. No.

Q. SmithKline did not distribute opioids?

A. To the best of my knowledge,

no. I don't believe we had any products that were opioids.

Q. And SmithKline did not distribute controlled substances?

A. Again, to the best of my recollection, we did not distribute any controlled substances.

Q. Now, you were promoted -- or excuse me. Let me strike that.

At some point SmithKline merged with Glaxo, correct?

A. That is correct.

Q. And you became the compliance officer?

A. I became the compliance officer for the global R&D business unit.

Q. You ensured that Glaxo -- and the new company was known as GlaxoSmithKline?

A. That's correct.

Q. And you ensured in your position that GlaxoSmithKline's global research and development operations complied with international regulatory

requirements?

A. Domestic and international, yes.

Q. Now, GlaxoSmithKline is a pharmaceutical manufacturer, correct?

A. Yes, sir, it is.

Q. GlaxoSmithKline is not a wholesale drug distributor?

A. That is correct.

Q. GlaxoSmithKline does not manufacture opioids?

A. No. GlaxoSmithKline does not manufacture opioids. But let us be clear, and especially in the research and development arm, they use opioids. Opioids are used in the testing. So, therefore, DEA compliance such as security controls, vaults, sign-ins, all that is absolutely relevant. And yes, I did work in that space.

Q. But -- and I appreciate that distinction. But GlaxoSmithKline does not manufacture opioids, correct?

A. That is correct.

Q. GlaxoSmithKline does not distribute opioids, correct?
A. Correct.
Q. GlaxoSmithKline does not distribute controlled substances?
A. That is correct.
Q. After GlaxoSmithKline, you became a director in the life sciences compliance department at Deloitte & Touche?
A. I did.
Q. Your LinkedIn page states that you had a special focus on bribery and corruption issues pertaining to research trials, and grants, medical affairs and medical science liaisons?
A. That was certainly one of the focuses. But I had -- again, my duties as a director of life sciences buttoned up around a bunch -- bunch of duties.
But, yes, my specialty was that particular area. I had a lot of expertise in that space.

A. Misonix.
Q. Misonix. I butchered that one, didn't I?
You became the interim chief compliance officer at Misonix?
A. I was interim chief compliance officer.
Q. You were there for about seven months?
A. Yes.
Q. And why -- why did you leave after seven months?
A. Because they no longer needed the services that I was providing. My job was to stand up and get the compliance program running for that -- it was a small company.
Q. It was a medical device company?
A. Medical device company on Long Island.
Q. Misonix is not a wholesale pharmaceutical distributor?
A. No, sir.

Q. Misonix does not manufacture opioids?
A. No.
Q. Misonix does not manufacture controlled substances, correct?
A. No, sir, it does not.
Q. Following your time at Misonix, you started the Whitelaw Compliance Group?
A. No, actually the Whitelaw Compliance Group predates my job -- my job at Misonix. And Misonix was part of -- was a consulting gig.
Q. Your current position is the president and CEO of Whitelaw Compliance Group, correct?
A. Correct. It's my company.
Q. Your company is described in your CV, as, "Focused exclusively to small to medium-sized FDA-regulated companies." Is that right?
A. That's -- that's the general direction that I work in, yes.
Q. You focus on small and

medium-sized FDA regulatory companies?

A. I do focus on them.

Q. Your company does not focus on compliance at large companies, correct?

MR. BOGLE: Object to form.

THE WITNESS: Typically, Chris, it doesn't, although I will do work for large companies. Typically the larger companies are looking for the Deloitte & Touches, the Pfizers. And the Pfizers of the world, GSKs of the world are looking for the large big four. I'm not trying to compete with the big four. That's not the services that I provide.

BY MR. EPPICH:

Q. I was looking at your company's website, specifically the advertised services that you advertise. And I saw that you -- you do not advertise services for pharmaceutical wholesale distributors, correct?

experiences or services concerning DEA on your website, do you?

A. Not that I rightly recall.

Q. Mr. Whitelaw, you never worked at the DEA, did you?

A. No, sir. I didn't. I didn't have the honor.

Q. You've never worked at a wholesale distributor?

A. No.

Q. Do you know how many wholesale distributors are in the United States right now?

A. No. Afraid I don't have a hard count for you.

Q. And you testified earlier that you've never designed a compliance program for wholesale distributor that's currently in use, correct?

A. No. That's not what I testified to. You asked me if I did controlled substances work. As far as designing compliance programs for others, yes, I have.

at any of the defendants named in this litigation?

A. Yes.

Q. Have you ever worked at a chain pharmacy?

A. No, sir.

Q. Have you ever designed a compliance program for a large chain pharmacy that is currently in use?

A. No, sir.

Q. Have you ever designed a controlled substance compliance program for a pharmaceutical manufacturer that is currently in use?

MR. BOGLE: Object to form.

THE WITNESS: Again, I can't answer that for you. I don't know.

BY MR. EPPICH:

Q. On your CV, I notice that your CV does not mention the Controlled Substances Act; is that true? Would you agree?

A. I would have to read it all

over again. Do you want to give me a minute to read it to make sure that I can answer that honestly?

MR. BOGLE: If you need to read it, you can read it.

THE WITNESS: No, it doesn't say the magic word "controlled substances" in my resumé.

BY MR. EPPICH:

Q. Your CV doesn't mention opioids, does it?

A. No, it doesn't have that magic word in there either.

Q. And it doesn't mention controlled substances?

A. I believe I just answered that question, and the answer is no, it does not.

Q. Your CV doesn't mention diversion of opioids at all either, does it?

A. No, sir, it does not.

Q. The DEA and the FDA, you're familiar with those agencies?

A. DEA and FDA?
Q. Yes, sir.
A. Yes, sir, I'm familiar with both agencies.
Q. And the DEA and the FDA are different federal agencies, correct?
A. Yes, that is correct.
Q. DEA and FDA have different regulatory focuses?
MR. BOGLE: Object to form.
THE WITNESS: So they have different regulatory focuses, but I would also qualify that there's overlap between the two, and the two work together in certain instances, controlled substances being an excellent example of that.
BY MR. EPPICH:
Q. Well, the DEA is the agency with primary responsibility for enforcing the Controlled Substances Act, correct?
A. With the Controlled Substances Act, yes.

Q. And the FDA is not the government agency charged with enforcing the Controlled Substances Act, correct?
A. That is --
MR. BOGLE: Object to form.
THE WITNESS: That is correct.
BY MR. EPPICH:
Q. FDA does not promulgate regulations under the Controlled Substances Act?
A. I'm sorry. Say that again, please.
Q. Does the FDA promulgate regulations under the Controlled Substances Act?
A. Not usually.
Q. Not ever, correct?
A. To the best of my knowledge, no.
MR. BOGLE: Chris, if you're shifting to another area, we've been almost an hour ten I think.
MR. EPPICH: Maybe ten more

A. To my knowledge, no, it's not a criminal case.

Q. And under the guideline's own applicability section, the guidelines are not applicable to this civil litigation.

Would you agree?

MR. BOGLE: Objection.

THE WITNESS: No, sir, I would not agree. I fundamentally disagree with where you are going with this.

The guidelines are the basic framework. They are where everybody starts. It's where industry starts. It's where compliance professionals start. It's where good companies start, et cetera.

It is the baseline. It has become the de facto set of standards that you start with when you're looking at and assessing corporate compliance programs.

A. Yes.
Q. The OIG guidances were not issued by DEA, correct?
A. No, they weren't.
Q. And the OIG guidances don't address the Controlled Substances Act or suspicious order monitoring?
MR. BOGLE: Object to form.
THE WITNESS: Could you rephrase the question, please?
BY MR. EPPICH:
Q. Do the OIG guidances address the Controlled Substances Act or discuss the Controlled Substances Act?
MR. BOGLE: Same objection.
THE WITNESS: Not in so many words, no. But again, I would go back to the conversation that we had earlier. You're reading this in a very narrow context. In the world of compliance, we look at a lot of guidance.
The OIG guidance, the Bard case, are all examples of putting

Q. You're fine. It's hard sometimes.

MR. BOGLE: Can you restate the question for him just so we're clear. I think he jumped on you.

MR. EPPICH: I will. I'm trying to restate it in my head first.

MR. BOGLE: Okay. That's fine.

BY MR. EPPICH:

Q. Dr. Whitelaw, are you aware of anyone who has ever used a scale such as the one that you prepared in Figure 2 to measure how a distributor complies with the Controlled Substances Act and its associated regulations?

A. Not in that context, no.

Q. Now, looking at -- looking at your model in Figure 2, is there a point system or some other system that you apply to evaluate the maturity of the compliance program?

A. There is not a strict

quantitative methodology. It's more of a qualitative assessment.

Q. And does your report reflect the nature of the qualitative assessment to move from say foundational to maturing, to advancing, to leading?

A. Yeah. I think if you look at the bullet points underneath there, and also if you look at the attributes that we discussed before, you will come up with that.

Q. So the attributes that we reviewed from Pages 28 to 42 and then the bullet points that we see here under Figure 2.

A. Right. They're all combined together.

Q. Now, have you applied Figure 2, your model, to the compliance programs that are used by the defendants in this litigation?

A. Yes. I believe we can go find the page citations. Yes, it was used.

GAO reports or any congressional testimony, to your recollection?

A. I don't recall. I honestly don't recall at this point.

Q. Now, sir, is it your opinion that companies should look to government guidances from the relevant regulatory agencies when designing their compliance programs?

A. Yes, they should.

Q. That would include the OIG guidances that you discussed in your report?

A. Yes.

Q. And perhaps even the DOJ updated guidance on evaluating corporate compliance programs that you discussed in your supplemental report?

A. Yes.

Q. Is it your opinion that companies should look at settlements and precedents when designing their compliance programs?

A. Yes.

Q. That would include the Rochester Drug Cooperative deferred prosecution agreement that we saw in your supplemental report?

A. Yes, sir.

Q. And the U.S. versus C.R. Bard plea agreement that you discuss in your report?

A. Yes, sir.

Q. And the federal sentencing guidelines that you discuss in your report?

A. Yes, sir.

Q. Have you always held this opinion, these opinions?

A. Have I always held these opinions?

Q. Yes, sir.

A. Ever since I've been a compliance officer, yes. Again, you use what's available to you to build an effective compliance program. All this material are data points that you can draw from in building an effective

compliance program.

Q. Now, you -- you actually held though, the opposite view about these opinions and about the value of looking at guidances from regulatory agencies, settlements, and prior precedents, right?

A. I'm not sure what you're talking about, so I -- you're going to have to be more specific, sir.

(Document marked for identification as Exhibit Whitelaw-8.)

BY MR. EPPICH:

Q. Let me introduce as Exhibit Number 8. Exhibit Number 8 is an article entitled "Government Standards Undermine Compliance Efforts in Life Science Companies," by Seth B. Whitelaw dated March 7, 2018. I'll hand you that, sir.

A. Yeah, let me see it.

Q. You are familiar with this article, sir?

A. I am. Is there something in

particular that we want to look at in it?

Q. Yeah. So we -- if we turn to Page 2.

A. Mm-hmm.

Q. And I'm looking at the fourth paragraph down. This was March 7, 2018. This was roughly six months before you were hired by the plaintiffs' counsel for your expert role in this case, correct?

A. That would be about right.

Q. On Page 2 of Exhibit 8, we -- we read, "Although the government remains steadfast, the companies must individually tailor their compliance programs to suit each business and organization. The OIG, among other enforcement bodies, continue" -- "continues to embrace settlement boilerplates and slowly increases the burden and complexity for compliance officers."

You previously wrote this sentence, didn't you?

something to have been done about it, and I don't see that.

BY MR. EPPICH:

Q. But, sir, you've testified that you have no DEA experience.

MR. BOGLE: Object to form. He said he didn't work for DEA.

THE WITNESS: This is not a DEA-relevant issue. This is a corporate compliance relevant issue. And even so, the question is, they were substantially in charge of these programs. And I have not seen McKesson take any appropriate action to remove the people who were supposed to be running the program correctly and overseeing it, and they're accountable. There's no accountability that I could see.

BY MR. EPPICH:

Q. Sir, you have no experience working in the compliance department at a pharmaceutical distributor, correct?

A. I have not worked for a pharmaceutical distributor, but I'm not sure how that's particularly relevant to this particular -- is particularly germane to this issue. Holding people accountable who are supposed to be running your compliance programs is pretty germane issue and simple issue across all the boards.

Q. Well, I think it's relevant, sir, because you took it upon yourself to name three of McKesson's employees in your report as employees that McKesson should have taken some form of disciplinary action against.

And I would like to know what basis you have for making these allegations in your report, sir?

MR. BOGLE: Object to form.

THE WITNESS: My experience --

MR. BOGLE: Go ahead.

THE WITNESS: My experience sitting here as a compliance

spot on the nonexistent remedial level of the maturity scale?

A. Again, I'd say by and large, yes.

Q. How can we tell that from your report? I mean, where do we look in your report to determine how far Walgreens is from making its way onto the foundational level of the compliance maturity scale?

A. I didn't put you -- I didn't put it on a graph, Counselor.

Q. That's why I'm asking the question, sir.

A. No, I did not put it on a graph.

Q. And so how are we supposed to know from your report how far off the scale we are?

A. I think you're missing the point. Is you're not even moving to the right-hand side of the scale, Counselor. You're not even halfway to moving toward an effective compliance program. You're

sitting at the left-hand edge. I think you are overcharacterizing it.

Q. I understand that's your position, sir. And I'm just trying to get an understanding of your opinions. And what I would like to know is, how, from your report, am I supposed to determine how far off to the left-hand side of the scale Walgreens is supposed to be?

A. And I guess what I'm trying to say to you is I'm not sure that being off to the left or how far off, if it's one inch or three inches. I think you're missing the point. You shouldn't be off to the left-hand side at all. You should be more towards the middle, to the right-hand side of the graph. That's the point.

Q. I understand that's your position, sir. My question is coming from a different place. I'm not asking right now what you think we should have done differently. I'm just trying to

understand how I'm supposed to know where you think we actually are.

A. I think I told you where I think you actually are.

Q. But there's -- as you said a moment ago, there's no graph or chart that shows where Walgreens falls with respect to the compliance maturity scale, correct? That's not in the report?

A. There is no point on the graph that I put Walgreens on, if that's what you're asking, Counselor, no.

Q. Turn if you would, please, to Page 183, which is the start of the Walgreens section.

A. I'm here.

Q. I notice you -- the heading on this Section 13 is "Walgreens Boots Alliance." Is that correct?

A. Correct.

Q. The focus of the first several paragraphs is also on Walgreens Boots Alliance, right?

A. And Walgreens too. It's a

have good quality documentation. I think that's a requirement. Otherwise how can you know what you've done or not done?

Q. Sir --

A. I can --

MR. BOGLE: Finish your answer. Are you done?

THE WITNESS: I'm done.

BY MS. SWIFT:

Q. Do you know what the word diversion is?

A. Yeah. If you want to get the precise definition we can go back to the front of the report.

Q. I'd like to know if you can give me a definition of diversion without looking at something in your report.

A. Again, to be absolutely precise, I would love to give you that. I'm going to go back to my report and rely on my report.

Q. It doesn't have to be that precise.

A. I'm going to rely on my

report.

MR. BOGLE: You can go to your report.

THE WITNESS: I'm going to go with my --

MS. SWIFT: I don't want to know the definition that he has in his report.

BY MS. SWIFT:

Q. What I would like to know is if you can give a definition without looking at your report. Yes or no?

A. I'm going to look at my report.

Q. Okay.

A. I want to look at my report.

Q. That's fine. We'll move on.

A. Okay.

Q. You haven't done any analysis of any order that Walgreens shipped to one of its pharmacies to determine whether that order led to drugs being diverted, correct, sir?

A. Again, Counselor, I'm not

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Continued videotaped deposition of DR. SETH B. WHITELAW, taken pursuant to notice, was held at the offices of Golkow Litigation Services, One Liberty Place, 1650 Market Street, Philadelphia, Pennsylvania, beginning at 8:31 a.m., on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

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A. Applied to an SOM program alone?

Q. Yes, have you ever found, when you applied it to a SOM program, have you found such a program to score above the foundational level?

A. No, I have not.

Q. Before you were engaged in this case, had you ever used this model to evaluate an SOM program?

A. No, I had not. But it is a standard compliance maturity model that I've used to evaluate compliance programs.

Q. But not an SOM program before you were --

A. Not an SOM --

Q. -- engaged in this case?

A. -- program, per se.

Q. I want to turn to --

MR. BOGLE: Just wait until he finishes.

BY MR. HYNES:

Q. -- CVS's distribution

reviewed at the Lumberton distribution center, right?

A. That's my recollection.

Q. By Mr. Mortelitti?

A. That is also my recollection.

Q. And you write he had no prior experience with suspicious order monitoring.

A. I can go back and look at the report, but yes, I recall that.

Q. Okay. But you also don't have any prior experience with suspicious order monitoring, do you?

MR. BOGLE: Object to form. Misstates testimony.

THE WITNESS: I'm not sure I understand what you mean. I do have experience working in regulated -- I did -- I have reviewed the requirements around being a suspicious order monitoring. If you asked if I built and designed a system, no, I

haven't. But that's already on the record.

BY MR. HYNES:

Q. You've never operated an SOM system either, have you?

MR. BOGLE: Object to form.

THE WITNESS: No. My role is -- no, I have not.

BY MR. HYNES:

Q. You've never audited an SOM system, have you?

MR. BOGLE: Object to form.

THE WITNESS: No, I have not audited an SOM system. But I have -- I have audited PDMA systems which are substantially similar.

BY MR. HYNES:

Q. But not an SOM system?

A. Not an SOM system.

Q. And you write that "CVS had one person doing the daily review of the IRR."

But there were people in the

A. I did look at it. It's footnoted in my report. So obviously I did look through it and look at it, yes.

Q. All right. So the compliance program for physicians is footnoted in your report is your recollection?

A. It is.

Q. Okay. Thank you. Now, you stated just a little while ago to Mr. Hynes that you've never operated or audited a suspicious order monitoring system; is that correct?

A. That is what I told him, yes.

Q. Okay. Do you consider yourself an expert on suspicious order monitoring?

A. I believe, based on the work that I have done, my 30 years' experience, all that I have reviewed, all the DEA guidance I have reviewed, my conversations with Mr. Rafalski, yes, I would say that I am qualified to be a

SOMs expert.

Q. And prior to your discussions with Mr. Rafalski, all of the documents that you reviewed for this litigation, all of the deposition transcripts, all of that work that you did for this litigation, would you have considered yourself a suspicious order monitoring expert?

MR. BOGLE: Object to form.

THE WITNESS: Could you be more -- again, could you repeat the question? I'm sorry. It's been a long day.

BY MR. DAVISON:

Q. Understood, sir. So prior to the work that you did for this litigation, which we've discussed included reviewing, you know, hundreds of thousands of documents, deposition transcripts, discussions with Mr. Rafalski, did you consider yourself a suspicious order monitoring expert?

MR. BOGLE: Same objection.

variety of different areas. I'm not sure that I reflected on it the way you're asking me to.

BY MR. DAVISON:

Q. Okay. Prior to this litigation, have you ever held yourself out to a potential client as a suspicious order monitoring expert?

A. Other than the work that I did on a proposal for Deloitte, which, again, was more of a compliance process assessment for suspicious order monitoring program, I don't recall ever putting that moniker on my name.

Q. So you didn't tell Henry Schein that you were an -- that you were an expert in suspicious order monitoring when you made that pitch, correct?

MR. BOGLE: Objection. Misstates testimony.

THE WITNESS: As I said, I think I answered your question as best I can. I don't have anything else to add to that answer.

A. From time to time, yes.

Q. All right. So Dr. Whitelaw's expectation is that manufacturers conduct reviews and audits of distributors on top of what DEA does, correct?

MR. BOGLE: Object to form.

THE WITNESS: They -- they are your customers. You should be aware of what they are doing and comfortable with the way they are acting. That is just good third-party management, which is part of an effective compliance program.

Again, when you go back to the federal sentencing guidelines, the front of the report, if we really want to discuss it in detail, yeah, my expectation was that you manage your own third parties as well and not just simply rely on the DEA.

BY MR. DAVISON:

What I'm saying is it's up to the manufacturer to incorporate it and they should make an effort to use that data.

Q. And, sir, with respect to using that data, it could be used differently by different manufacturers, correct?

MR. BOGLE: Object to form.

THE WITNESS: Could you -- could you restate the question for me, please?

BY MR. DAVISON:

Q. Sure.

Under the -- the Dr. Whitelaw good manufacturers controlled substances compliance program -- or excuse me, anti-diversion compliance program --

A. You mean under the attributes that I list in my report that I gleaned from experience in the federal sentencing guidelines and Controlled Substances Act, et cetera? Is that what

we're referring to?

Q. The attributes that are listed in your report on Page 36.

A. Okay. Great.

Q. You don't define a way that you expect manufacturers to monitor chargebacks, correct?

A. No, I do not define a specific way for...

Q. Are you aware of DEA ever suggesting a specific metric or method that manufacturers are to use in analyzing chargeback data?

MR. BOGLE: Object to form.

THE WITNESS: No, I am not aware of DEA ever suggesting a specific methodology to analyze and review chargeback data.

BY MR. DAVISON:

Q. So under the expectations that you have for a manufacturer's program, is one way the manufacturer could utilize chargeback data to utilize the data to look at its distributors and

A. It does.

Q. And you state that "a manufacturer should instruct and require its sales representatives and inhouse field support and marketing personnel to provide any observations of potential diversionary behavior to their inhouse compliance department for further evaluation and potential action," correct?

A. That is correct.

Q. And, sir, is -- is this something that's explicitly laid out in the CSA?

A. It is embedded in the CSA.

Q. And it's embedded under those -- those four words of controls against effective diversion, correct?

MR. BOGLE: Object to form.

THE WITNESS: Yes, as well as under the federal sentencing guidelines of what an effective compliance program looks like as well, so...

somehow monitor physicians, correct?

A. I'm not saying that you have to create a sales force. I'm saying again the whole gist of this is you have available information, if you have boots on the ground, if you have people out there who are observing behavior and they see something that's troubling, you know, it's about as basic as what you see on Amtrak these days. If you see something, say something.

Q. And all of that -- that obligation, again, comes from the four words "effective controls against diversion," right?

A. It comes from the federal sentencing guidelines together with the four words of "effective controls against diversion," yes.

Q. You also mention IMS data, correct?

A. Is there a particular section that you're looking at?

Q. Yeah. Page 43. At the top.